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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,116	07/19/2005	Jean-Francois Zagury	ZAGURY9	7529
<div>1444      7590      07/13/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303</div>				
			EXAMINER MERTZ, PREMA MARIA	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 07/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,116	<b>Applicant(s)</b> ZAGURY, JEAN-FRANCOIS	
	<b>Examiner</b> Prema M. Mertz	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-19, 24-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 14 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/4/04</u> . | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

1. Claims 2-13 have been canceled (5/31/07). Amended claims 1 and 14 and new claims 15-25 are pending in the instant application.

#### ***Election/Restrictions***

2. Applicant's election with traverse of Group 6 (claims 1-11 and 14, drawn to the fragment of hTNF alpha of SEQ ID NO:6) in the reply filed on 5/10/2007 is acknowledged.

The traversal is on the ground(s) that the restriction is improper since the claims exclude SEQ ID NO:1 from the claims. This argument is not found persuasive because the searches for the different sequences in the claims would not overlap. The inventions listed in the different Groups do not relate to a single general inventive concept because they lack the same or corresponding special technical features for the following reasons. With respect to the elected peptide of amino acid sequence set forth in SEQ ID NO:6, the peptide lacks either a common structural property which distinguishes it as a Group from structurally related compounds of the prior art or which provides it with a common utility which is lacking from those of the prior art. The special technical feature of the invention encompassing the peptide of SEQ ID NO:6 is the amino acid sequence of SEQ ID NO:6. The other peptides listed do not share the special technical feature (SEQ ID NO:6) because the other peptides are structurally and functionally different. As shown on pages 4-6 of the instant specification, the different peptides are structurally and functionally different and examination of all these peptides would place undue examination burden on the Examiner.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and

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examine multiple inventions in a single invention. The different peptides are related as different products which are independent and distinct, each from the other, which possess characteristic differences in structure and each has an independent utility, that is distinct for each invention which cannot be exchanged.

Lastly the inventions are distinct because a search of the literature for the peptide of SEQ ID NO:6, would not necessarily be expected to reveal art for all the other peptides, which searches are extensive requiring separate searches which would be unduly burdensome.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different and recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement (3/12/07) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

However, since SEQ ID NOS: 5, 6, 7, 39 are all related to TNF $\alpha$  fragments, claim 1 and dependent claims 14, 20-23 will be examined in the instant application.

Claims 15-19, 24-25, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Specification***

2. A new title of the invention is required because the word “novel” is not considered as part of the title of an invention and the Patent and Trademark Office does not include such words at the beginning of the title of the invention. It is suggested that the word “novel” be deleted from the title of the invention to read “cytokine peptides”. See MPEP § 606.01.

***Claim Rejections - 35 USC § 112, second paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 14, 20-23, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as vague and indefinite because of several reasons.

Claim 1, line 4, is vague and indefinite because it recites “at least one of its atoms”. Does this encompass one of the atoms of the peptide or of the amino acid of the peptide?

Claim 1 recites the limitation "the spacing d" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 1, line 2, is vague and indefinite because it recites “5 to 30 amino acids”. However, line 11, recites “SEQ ID NO:5” which is 35 amino acids. Similarly, claim 1, line 2, is vague and indefinite because it recites “5 to 30 amino acids”. However, line 11, recites “SEQ ID NO:26” which is 36 amino acids. Appropriate correction is requested.

Claims 14, 20-23, are rejected as vague and indefinite insofar as they depend on rejected claim 1 for their limitations.

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***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4a. Claims 1, 14, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,440,694 ('694 patent).

The reference teaches a amino acid fragment of TNF- $\alpha$  which is 100% identical to the peptide of amino acid sequences set forth in SEQ ID NO:7 contained in an amino acid fragment 24 amino acids in length. A comparison of the claimed peptide of SEQ ID NO:7 and the peptide of the reference is set forth below. Therefore, the reference anticipates instant claims 1, 14, 22.

Query Match 100.0%; Score 74; DB 2; Length 24;  
Best Local Similarity 100.0%; Pred. No. 1.5e-06;  
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1 FQLEKGDRLSAEINR 15
Db	10 FQLEKGDRLSAEINR 24

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4b. Claims 1, 14, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,440,694 ('694 patent).

The reference teaches a amino acid fragment of TNF- $\alpha$  which is 100% identical to the peptide of amino acid sequences set forth in SEQ ID NO:7 contained in an amino acid fragment 24 amino acids in length. A comparison of the claimed peptide of SEQ ID NO:7 and the peptide of the reference is set forth below. Therefore, the reference anticipates instant claims 1, 14, 21.

Query Match 100.0%; Score 74; DB 2; Length 24;  
Best Local Similarity 100.0%; Pred. No. 1.5e-06;  
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1 FQLEKGDRLSAEINR 15
Db	10 FQLEKGDRLSAEINR 24

### ***Conclusion***

No claim is allowed.

Claims 1, 14, 20-23 are rejected.

### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D., J.D.  
Primary Examiner  
Art Unit 1646  
June 20, 2007